

STATE OF CALIFORNIA

)NTR ACT MANDATORY

CONTRACT NUMBER:

1-06-68-17

DESCRIPTION:

SOLID STATE IMMUNOASSAY

SYSTEM-DOJ USE ONLY

CONTRACTOR:

IMMUNALYSIS CORPORATION

EFFECTIVE DATES:

8/24/2006

THROUGH

8/23/2008

SUPERSEDES CONTRACT NO.: 1-05-68-17

AREA:

SACRAMENTO (DOJ)

DISTRIBUTION:

BY DOJ

* TAX:

Add appropriate sales and use tax. Exempt from Federal Excise Tax.

*Food contracts are tax exempt.

IILTON, Deputy Director

Use of this agreement by all agencies is mandatory with monetary exceptions stated herein or contained in State Administrative Manual.

To obtain assistance or report non-compliance by supplier, or for any suggestions or recommendations write:

Department of General Services, Procurement Division, P.O. Box 989054, W. Sacramento, CA 95798-9054, or call: Contract Administrator, SHERRY JACOBS 916-375-4450, CALNET 480-4450

Contract (Mandatory): 1-06-68-17

SUPPLIER ID: NAME: ADDRESS: 679251 IMMUNALYSIS CORPORATION 829 TOWNE CENTER DRIVE POMONA, CA 91767

CONTACT:
FAX NUMBER:
TERMS OF PAYMENT:
FOB:
MINIMUM ORDER:

909-482-0840 J 909-482-0850 Net Destination AS SPECIFIED

JIM SOARES

STATE OF CALIFORNIA DEPARTMENT OF GENERAL SERVICES PROCUREMENT DIVISION

Contract (Mandatory): 1-06-68-17

ITEM COMMODITY NO. SUPPLIER UNIT NO. SUPPLIER PART NO. NO.	UNIT PRICE
6810-297-7200-1 679251 KT CHEMICAL ASSAY KIT Immunoassay Solid Phase EIA, <u>Opiates</u> 480 tests/kit per the attached specifications and special terms and conditions. Cost to include the solid-state enzyme immunoassay system. As noted herein, including instrumentation, installation, training, maintenance, and loan equipment	345.6000
SEE ALSO ATTACHMENT "A", STATEMENT OF WORK.	
6810-297-7200-1 679251 KT CHEMICAL ASSAY KIT Immunoassay Solid Phase EIA, Cocaine 480 tests/kit per the attached specifications and special terms and conditions. Cost to include the solid-state enzyme immunoassay system. As noted herein, including instrumentation, installation, training, maintenance, and loan equipment (if necessary), as noted herein.	345.6000
SEE ALSO ATTACHMENT "A", STATEMENT OF WORK.	
6810-297-7200-1 679251 KT CHEMICAL ASSAY KIT Immunoassay Solid Phase EIA, Phencyclidine 480 tests/kit per the attached specifications and special terms and conditions. Cost to include the solid-state enzyme immunoassay system. As noted herein, including instrumentation, installation, training, maintenance, and loan equipment (if necessary), as noted herein.	345.6000
SEE ALSO ATTACHMENT "A", STATEMENT OF WORK.	

STATE OF CALIFORNIA DEPARTMENT OF GENERAL SERVICES PROCUREMENT DIVISION

Contract (Mandatory): 1-06-68-17

UNIT PRICE	345.6000	345.6000	
ITEM COMMODITY NO. SUPPLIER UNIT DESCRIPTION NO. NO. NO.	4 6810-297-7200-1 679251 KT CHEMICAL ASSAY KIT Immunoassay Solid Phase EIA, Methambhetamine.480 tests/kit per the attached specifications and special terms and conditions. Cost to include the solid-state enzyme immunoassay system. As noted herein, including instrumentation, installation, training, maintenance, and loan EQPT (if necessary), as noted herein.	SEE ALSO ATTACHMENT "A", STATEMENT OF WORK. 5 6810-297-7200-1 679251 KT CHEMICAL ASSAY KIT Immunoassay Solid Phase EIA, Benzodiazepines 480 tests/kit per the attached specifications and special terms and conditions. Cost to include the solid-state enzyme immunoassay system. As noted herein, including instrumentation, installation, training, maintenance, and loan equipment (if necessary), as noted herein.	SEE ALSO ATTACHMENT "A", STATEMENT OF WORK.

Contract (Mandatory): 1-06-68-17

UNIT PRICE	345.6000	69.1200	VARIABLE
ITEM COMMODITY NO. SUPPLIER UNIT DESCRIPTION NO. NO. NO.	6 6810-297-7200-1 679251 KT CHEMICAL ASSAY KIT Immunoassay Solid Phase EIA, <u>Cannabinoids</u> 480 tests/kit per the attached specifications and special terms and conditions. Cost to include the solid-state enzyme immunoassay system. As noted herein, including instrumentation, installation, training, maintenance, and loan equipment (if necessary), as noted herein.	SEE ALSO ATTACHMENT "A", STATEMENT OF WORK. 7 6810-297-7200-1 679251 KT CHEMICAL ASSAY KIT Immunoassay Solid Phase EIA, LSD 96 tests/kit per the attached specifications and special terms and conditions. Cost to include the solid-state enzyme immunoassay system. As noted herein, including instrumentation, installation, training, maintenance, and loan equipment (if necessary), as noted herein.	SEE ALSO ATTACHMENT "A", STATEMENT OF WORK. 8 6810-909-0000-9 679251 VA CHMICL-DGS/PROCUREMENT USE ONLY
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Scope:

This contract covers the mandatory estimated biennial (two-year) requirement for Department of Justice for Solid State Enzyme Immunoassay System.

Extraordinary Extension Option:

In the event of an extraordinary circumstance the State may extend the contract for up to an additional year beyond the stated term and any noted extensions. Extensions during this period may occur in increments until the establishment of a new contract (not to exceed one-year). Exercise of this may occur in the event that a **replacement** contract cannot be established due to the protest of intent to award, or loss of key procurement staff, or extraordinary circumstance that would otherwise cause an unanticipated disruption in the contracting process.

If necessary, prices may be increased during an extraordinary extension option period, to the extent that the price is determined to be "fair and reasonable." Requests for price increase(s) shall include substantiated information to support the proposed increase (e.g., manufacturer's price list, significant changes in published market indicators for the industry, certified raw material cost data, and any other substantiating information as requested by State). In no event will price increases be accepted with retroactive effective dates.

Immunalysis Corporation will accept orders by Facsimile or E-mail transmission:

Facsimile Number: (909) 482-0850

E-Mail Address: order@immunalysis.com

Vendor Contact Name: John Ellsworth

Vendor Contact Telephone Number: 888-664-8378 – Ext. 16

Price:

Price shall be firm for the duration of the contract.

Delivery/Installation:

<u>System installation</u> shall occur within 90 days ARO of contract issuance. <u>Reagents</u> shall be delivered within 10 days ARO.

Minimum Order:

The minimum order is one (1) assay kits from each of the first six (6) line items each month. (Each kit consists of 15 plates of 96 wells each—480 tests per kit. There is no minimum order for line item seven (7). Assay kits for LSD will be ordered on an as needed basis; assay kits for LSD consist of 3 plates of 96 wells each.

Quantity Estimates:

Quantities shown for each line item are estimates and are for evaluation purposes only. Actual purchases may vary from this pattern. The State will not be obligated to purchase contractor's excess inventory of any line item if actual purchases vary from the anticipated purchase pattern.

Ordering Procedures:

Department of Justice Ordering Procedures:

Issue state agency orders to the contract supplier. State agencies will be sending a Contract/Delegation Purchase Order (STD. 65). The DGS's fee for state agency use is available in the Price Book, located on the Department of General Services, website at www.ofs.dgs.ca.gov/Price+Book/P/Purchasing.htm.

For billing send a copy of your purchase order to:

DGS-Procurement Division Attn: Data Entry Unit PO Box 989052 West Sacramento, CA 95798-9052

Product Quality:

Commodities received shall in all cases be in accordance with first quality standards, First Quality Standards means the products need to have been quality controlled by the manufacturer to ensure they will work properly. Commodities shall be free from any defects affecting serviceability. Items not meeting these standards will be returned at supplier's expense. No substitutions of products may be made without previous written approval by the Department of General Services, Procurement Division.

Packaging:

Exterior packaging is to show the contents and the purchase order number. All the packaging is to conform to the applicable freight classifications, Surface Transportation Board and/or postal regulations, and is to be of a quality to assure final delivery without damage to the contents.

<u>Consumable Supplies:</u> Pricing may be increased over the life of this contract for these consumable supplies, so long as any increases can be demonstrated as "fair and reasonable". Consumable supplies would be items such as pump tubing or probes.

Supply Description	Part Number	List Price	State Price	
1000 ul Syringes	71-502	\$ 150.00	\$ 130.00	
STD Telflon Coated Tip	71-100	\$ 125.00	\$ 115.00	
Ceramic Tip	71-712	\$ 400.00	\$ 400.00	
Reagent Troughs (100 pcs)	70-744	\$ 250.00	\$ 250.00	
Valves for dilutors	71-701	\$ 150.00	\$ 150.00	
Preventive Maintenance Kit	71-301	\$ 3000.00	\$ 2800.00	

Catalog Part List Name/Number for above items: Immunalysis Consumerables Part List 2005

Brand: Tecan Model: Genesis 150/8 RMP

Invoicing Requirements:

The contractor is to render invoices as instructed on individual orders. Invoices shall include the order number, the contract number, the commodity code number, quantity, unit price, and extensions. State sales and/or use tax is to be added to each invoice.

Usage Reports:

The contractor is required to submit a detailed usage report and hard copies of each purchase
order placed against the contract for the respective quarter. Usage Reports are required to be submitted every three months commencing from the date of the contract award. This report is to include the total quantities per item, item description per contract item number, and a grand total for the period. Failure to submit completed usage reports in a timely manner may be considered a breach of contract and subject the Contractor to General Provision 26, Rights and Remedies of the State for Default.

Send the Contract Usage Report with purchase orders to the following address:

Department of General Services
Procurement Division
Attn: Sherry Jacobs
P.O. Box 989054
707 3rd Street
West Sacramento, CA 95798-9054

Contractor Location:

Company Name: Immunalysis Corporation

Street Address: 829 Towne Center Drive

City, State, and Zip: Pomona, Ca. 91767

Person to contact: John Ellsworth

Phone No.: 909-482-0840

Fax No.: 909-482-0850

Emergency Purchases:

In the event of an emergency, the State may purchase any required line item from other than the contractor.

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SPECIFICATIONS FOR A SOLID-PHASE ENZYME IMMUNOASSAY SYSTEM FOR THE DETECTION OF DRUGS IN BIOLOGICAL FLUIDS

This IFB will result in a new 2 year contract with the State to provide Immunoassay Kits, instruments and all necessary hardware, software and all other necessary supplies to analyze biological samples for each of the following drugs:

Opiates
Methamphetamine
Benzodiazepines
Cocaine
Phencyclidine
THC (Marijuana/Cannabinoids)
Lysergic Acid Diethylaminde (LSD)

STATEMENT OF WORK:

The bid price to include the following:

I) Immunoassay kits plus shipping as described in this document.

II) Analytical Instruments, all necessary software(s), and software updates and revisions as described in section II of this document. The contractor retains title to the equipment.

III) Shipping charges and system installation.

- IV) The system must be maintained as described in Attachment B.
- V) Training

I) Immunoassay Kits

The acceptable range for the Observed Density (OD) on the zero calibrator shall not be less than 1.500 or greater than the maximum for the reader (minimum 4.000). Lot-to-lot variation of the OD on any assay shall not exceed twenty (20) percent.

These materials must be compatible with the analytical instrumentation described in Section II and utilize solid-phase enzyme immunoassay (EIA) for all the drug classes listed. The California Department of Justice does <u>not</u> want a custom-made immunoassay kit. The analysis of whole blood for the drugs listed below must be performed without precipitation or pretreatment of the whole blood. A blood or urine sample diluted 1:10 shall have meet or exceed the following sensitivity and cross-reactivity specifications. The drug detection assay must meet or exceed the following sensitivity and cross-reactivity specifications:

A. OPIATES

Sensitivity

- 5 ng/ml (Morphine)
- Must obtain 50% binding or less (50% displacement or greater) of free Morphine at 10 ng/ml using a diluted whole blood sample volume of no more than 25 μl.

Specificity

The following compounds will cross-react with this assay with at least the indicated percentages.

COMPOUND	% CROSS-REACTIVITY
Codeine	133
Morphine	100
Morphine-3-glucuronide	<5 ·
Hydrocodone	>33
Hydromorphone	17
Levorphanol	2

B. METHAMPHETAMINE

Sensitivity

- 10 ng/ml (d-Methamphetamine)
- Must obtain 50% binding or less (50% displacement or greater) of d-Methamphetamine at 50 ng/ml using a whole blood sample volume of no more than 10 μl.

Specificity

The following compounds will cross-react with this assay with at least the indicated percentages.

COMPOUND	% CROSS-REACTIVITY
d-Methamphetamine	100 <3
1-Methamphetamine d-Amphetamine	<3 <1
Ephedrine	<1
Fenfluramine Methyldioxamphetamine (MDA)	<1 <1
Methylenedioxmethamphetamine (MDMA)	>100
Pseudoephedrine	<1

C. BENZODIAZEPINES

Sensitivity

5 ng/ml (Oxazepam)

• Must obtain 50% binding or less (50% displacement or greater) of Nordiazepam at 100 ng/ml using a diluted whole blood sample volume of no more than 10 μl.

Specificity

The following compounds will cross-react with this assay with at least the indicated percentages.

COMPOUND	% CROSS-REACTIVITY
Alprazolam	>100
Chlordiazepoxide	<1
Clonazepam	<1
N-Desalkylflurazepam	<1
Diazepam	>100
Flunitrazepam	>100
Flurazepam	<1
Nitrazepam	>100
Nordiazepam	>100
Oxazepam	100
Temazepam	300
Triazolam	50

D. COCAINE

Sensitivity

- 5 ng/ml (Benzoylecgonine)
- Must obtain 50% binding or less (50% displacement or greater) of Benzoylecgonine at 150 ng/ml with a diluted whole blood sample volume of no more than 10 μl.

Specificity

The following compounds will cross-react with this assay with at least the indicated percentages.

COMPOUND	% CROSS-REACTIVITY
Benzoylecgonine	100
'Cocaethylene (EthylBenzylEcgonine)	2 `
Cocaine	16
Ecgonine	3
Ecgonine Methyl Ester	2

E. PHENCYCLIDINE

Sensitivity

• 4 ng/ml (Phencyclidine)

• Must obtain 50% binding or less (50% displacement or greater) of Phencyclidine at 10 ng/ml with a diluted whole blood sample volume of no more than 25 μl.

Specificity

The following compounds will cross-react with this assay with at least the indicated percentages.

COMPOUND			% CRO	SS-REACTI	VITY -
Phencyclidine	-		100		
4-Hydroxy Phencyclidine		:	<1		

F. THC (Marijuana/Cannabinoids)

Sensitivity

• 0.5 ng/ml (11-Nor-9-Carboxy-Delta-9-Tetrahydrocannabinol)

• Must obtain 50% binding or less (50% displacement or greater) of 11-Nor-9-Carboxy-Delta-9-Tetrahydrocannabinol at 30 ng/ml with a diluted whole blood sample volume of no more than 25 ul.

Specificity

The following compounds will cross-react with this assay with at least the indicated percentages.

COMPOUND	* .	% CROSS-REACTIVITY
Delta-8-Tetrahydrocannabinol		6
Delta-9-Tetrahydrocannabinol		10
Cannabidiol		<1
L-11-Nor-9-Carboxy-Delta-9-		100
Tetrahydrocannabinol		
Cannabinol		1

G. LSD

COMPOUND	V.	% CROSS-RE	ACTIVITY
Lysergic Acid Diethylami	nde (LSD)	100	
Lysergic Acid		<1	
Lysergic Acid Methyl-Ppr	opyl Amide	5.6	
Lysergic Acid Hydroxy-E	tthly Amide	<1	
Ergotamine Tartrate		<1	•

II. ANALYTICAL INSTRUMENTS

The system shall be supplied on a turnkey basis.

A. Automated Pipetting Station Minimum Requirements

- 1. Automated Pipetting Station shall perform fast batch transfer of blood and urine samples between standard 12 x 75mm, 12 x 55mm, or 10 x 75mm tubes and 96-well antibody-coated microtiter plates at least one row at a time.
- 2. Automated Pipetting Station shall also dispense reagents and buffers into microtiter plate wells.
- 3. Automated Pipetting Station shall have permanent, positive displacement, nonstick (e.g., Teflon® or ceramic) coating inside and outside (referred to as permanent nonstick tips hereafter), aspiration tips in sufficient number to dispense sample, or reagent, into microtiter plate wells plate at least one row at a time.
- 4. Automated Pipetting Station shall have a dedicated syringe or pump for each for the permanent nonstick tips.
- 5. Automated Pipetting Station shall be programmed to dispense multiple aliquots of sample to six separate microtiter plates from a single aspiration.
- 6. Automated Pipetting Station shall be programmed to perform a decontamination of the permanent nonstick tips sufficient to ensure no carry-over from 100,000 nanograms per milliliter before proceeding to the next row of samples
- 7. Automated Pipetting Station shall be programmed to multiple dispense buffer or reagent to assigned 96-well antibody-coated microtiter plates.
- 8. Automated Pipetting Station shall have user-definable options for adjusting sample aspiration rate, sample size, and dispense rate.
- 9. Automated Pipetting Station shall have liquid level detection capability to avoid aspirating solids. Greater weight shall be given to Automated Pipetting Stations featuring simultaneous liquid level tracking during aspiration of sample and reagent.
- 10. Automated Pipetting Station shall have a station onboard to wash inside and outside of aspiration tips to the level of zero carryover of 100,000 nanograms per milliliter before aspirating sample and after last dispense of sample (See #6).
- 11. Automated Pipetting Station shall have a barcode reader for sample tubes and microtiter plates and the ability to download barcode and sample status information to the laboratory's Data Management System on a Local Area Network and generate a batch report of the samples with their results of each assay performed.
- 12. Automated Pipetting Station shall have user-definable speed control for aspirating and dispensing sample or reagent (see #9).

- 13. Automated Pipetting Station shall require a single PC compatible CPU and monitor to operate all systems and be compatible with Windows 2000® operating system or newer.
- 14. The automated pipetting station shall have the ability to add 10 50 ul of sample (1:3, 1:5, or 1:10 prediluted blood, urine, or tissue homeogenate), and 100 to 125 ul of enzyme conjugate to each of the 96 wells in the microtiter plates of six assays with a decontamination step between each aspiration of sample.
- 15. If the automated pipetting station has an onboard plate washer, the wash station on the automated pipetting station shall have the ability to program dispensing speed, volume, aspiration, and number of cycles per wash.
- 16. If the automated pipetting station has an onboard plate reader, the microtiter plate reader on board the automated pipetting station shall have the ability to perform not only end-point reactions but also kinetic rate reactions in the microtiter plate. The plate reader shall have the ability to perform the above tasks in a standalone mode.
- 17. The automated pipetting station manufacturer or contractor shall have a response time to instrumentation problems of no more than two (2) hours by telephone and no more than twenty-four (24) hours for a service engineer to arrive for repairs if the service engineer's home base is on the eastern coast of the United States otherwise the engineer will arrive in twelve (12) hours.

B. Automatic Microtiter Plate Washer

- 1. The automatic microtiter plate washer shall be able to accommodate 96 well microtiter plates with a configuration of eight wells to a strip and twelve strips to a plate. If the plate configuration changes to a twelve wells to a strip and eight strips to a plate, the contractor shall be responsible for supplying the necessary washer manifold to accommodate this configuration.
- 2. The washer manifold shall have a dedicated dispensing port and aspiration port for each well on the strip.
- 3. The washer shall be a positive-pressure-type washer and wash either one strip at a time (strip washer) or twelve strips at a time (plate washer). If the washer is not on the automated pipetting station, the Department of Justice requests two washers (one strip washer and one plate washer) to be included in the bid. If the washer is part of the automated pipetting station, the Department of Justice requests that a strip washer be included in the bid.
- 4. The program for the microtiter plate washer will allow for controlling the flow rate of the wash, the volume of fluid to dispense, the rate of aspiration of the fluid from the well, adjust the soak times, and the number of washes per cycle.
- 5. The microtiter plate washer shall have standalone capabilities.
- 6. The automatic microtiter plate washer shall perform a six-cycle wash on a full 96-well microtiter plate in less than three (3) minutes.

C. Microtiter Plate Reader

- 1. The microtiter plate reader shall have the capability to do both kinetic and end-point reactions.
- 2. The microtiter plate reader shall read kinetic rate reactions with an interval time of five (5) seconds
- 3. The microtiter plate reader shall have the capability to do dual wavelength reading with a time interval of eight (8) seconds.
- 4. The microtiter plate reader shall have a halogen lamp as its light source.
- 5. The microtiter plate reader shall have a wavelength range from 340 to 750 nm.
- 6. The microtiter plate reader shall have an absorbance range from 0 to 4.000 Observed Density (OD) with a resolution of at least 0.001 OD.
- 7. The microtiter plate reader shall have an accuracy of better than +/- 1% and +/- 0.010 OD from 0.000 2.00 OD at a wavelength of 492 nm and better than 1.5% and 0.010 OD from 2.00 3:00 OD at a wavelength of 492 nm.
- 8. The microtiter plate reader shall have a linearity better than 1% between 0.000 -2.000 OD and better than 1.5% between 2.000 3.00 OD at wavelengths between 400 750 nm.
- 9. The microtiter plate reader shall have a reproducibility of better than +/- 0.5% and 0.005 OD from 0.000 2.000 OD at a wavelength of 492 nm and better than +/- 1.0% and 0.005 OD from 2.000 3.00 OD at a wavelength of 492 nm.
- 10. The contractor shall supply detector filters for at least the following wavelengths: 405 nm, 450 nm, 490 nm, and 650 nm.
- 11. The contractor shall be responsible for supplying the filters necessary to perform the analyses should the contractor change its protocol.
- 12. The microtiter plate reader shall be able to agitate the microtiter plates.
- 13. The microtiter plate reader shall have at least one RS232 25-pin bi-directional serial interface and one parallel Centronics printer interface.
- 14. If the automated pipetting station has a microtiter plate reader on board, it must have the capabilities to perform in a standalone mode. The Department of Justice requests that a standalone microtiter plate reader be included in the bid.

D. Plate Rotator(s)

1. The California Department of Justice requests that the automated pipetting station have the capabilities to rotate at least six plates, be variable speed. If the automated pipetting station does not have a rotator on board, the contractor shall supply the California Department of Justice with the necessary rotator(s).

E. Data Management System

- 1. The California Department of Justice Toxicology Laboratory shall supply one PC with a WindowsXP operating system on a Novell tm network using a Justice Trax un, an Oracle® database, evidence tracking system.
- 2. The contractor is responsible for ensuring the data from the barcode reader correlates with the results of assay(s) and download into the Justice Trax[®] evidence tracking system.
- The contractor is responsible for software that will generate raw OD's for each sample, calculating the ratio (OD standard/ OD unknown), and calculating the concentration (Ratio x Concentration of the standard). The data reduction software shall have the capabilities to perform the necessary calculations (Standard Deviation, Percent Coefficient of Variation, Percent Bound, Ratio, and the Concentration) on both blood and urine samples using both blood cutoff calibrator for blood samples and a urine cutoff calibrator on urine samples on the same plate on the same run. The data reduction software will be able to calculate the Coefficient of Variation and the Standard Deviation on a positive control placed in various positions within a run. There are to be no wasted wells to accomplished these calculations on a run. The data reduction software shall perform the following calculations on a control material located in five (5) various location throughout the plate to monitor drift:

Mean, Standard Deviation, Percent Coefficient of Variation, Percent Bound, Concentration"

- 4. The contractor is responsible for programming that will allow the analyst to print a final report containing, at minimum, the sample identification, the assay tested with result of negative (-), positive (calculated concentration), and a plus/minus result (+/-) for all the assays performed on the sample(s). The software must be able to generate a comma delimited ASCII file to be saved in a specific location for uploading into Justice Trax Im. Results should be editable before they are downloaded to the Justice Trax Im vidence tracking system. The analyst shall be able to select which sample(s) or case(s) to print in a final report (see Attachment D).
- 5. The final report shall include the Analyst's Name along with the date of the analysis along the top of the report. The final report will also include a "page of page" along the bottom of the final report (see Attachment D). The analyst shall be able to edit the report to indicate if a result is +/- or indicate if the sample is urine or some matrix other than blood (see Attachment D).
- 6. The contractor will have a thirty (30) day trial period from the day the instrumentation is installed to ensure all the conditions have been met.
- 7. The contractor must also provide all software updates and revisions free of charge during the term of the contract.

III. INSTALLATION

Installation of the EIA microtiter plate drug detection system must be provided at no cost to the State. Installation requires the contractor to meet the following obligations and requirements:

- A. At least 60 days prior to the actual delivery of the EIA system, the contractor must deliver to the Toxicology Laboratory in writing, a list of preinstallation requirements. This list shall include items such as operating environment, power requirements, water requirements, space requirements and site preparation details.
- B. Installation shall not occur until the <u>complete</u> **EIA** system, including all software, peripherals and accessories, are delivered to the Toxicology Laboratory. The manufacturer must provide all necessary manuals for this system.
- C. A factory trained service representative will perform the installation.
 - 9. After installation, the manufacturer must demonstrate that the entire system is compliant and is in an acceptable working condition.

IV. SYSTEM MAINTENANCE

As described in Attachment B.

V. TRAINING AGREEMENT

The contractor shall provide training in the use of the EIA system and software. Upon mutual agreement one person from the Toxicology Laboratory will be trained at the manufacturer's training facility. All costs including transportation are to be borne by the contractor.

VI. PERFORMANCE ACCEPTANCE TESTING

The EIA drug testing system will be used by the Department of Justice Toxicology Laboratory for the screening of drugs and their metabolites in biological samples. To adequately perform these tasks, the system must meet the following post-installation performance testing specifications:

- A. The system must successfully analyze a batch of 96 samples composed of both blood and urine matrices. The samples will be selected by the Toxicology Laboratory and will include standards with levels set at the sensitivity concentrations listed in Section II of these specifications and samples that contain unknown drugs at various concentrations. The system must correctly identify all of the drugs present with no false-positive results. Analysis of whole blood samples must be accomplished without prior pre-treatment. All sample and reagent transfer to microtiter plates must be accomplished by the automatic pipetting station with the same or better performance than indicated in Section I (A) of these specifications.
- B. Acceptance testing is intended to ensure that the equipment acquired (complete system including software) operates in substantial accord with the contractor's technical specifications, is adequate to meet the State's performance specifications, and evidences a satisfactory level of performance reliability prior to its acceptance by the State.
- C. Acceptance testing shall commence after the installation of the equipment and shall end when the equipment has met the standards of performance outlined above.
- D. In the event the equipment does not meet the standards of performance during the initial thirty (30) consecutive days after the start of the acceptance testing, the State shall have the option to request replacement equipment, extend the performance period, or terminate the order.
- E. Equipment shall not be accepted by the state and no charges associated with such equipment shall be paid by the state until the equipment has satisfactorily completed the acceptance tests.

Attachment B

SCOPE OF MAINTENANCE SERVICES

The contractor shall maintain the system in good operating condition during the life of the contract. The contractor will be responsible for all labor cost, travel, per diem, materials, nonconsumable supplies, transportation, equipment, and every other item of expense necessary to perform preventative and remedial maintenance of the equipment specified on Attachment A, section II, for the California Department of Justice, Toxicology Laboratory located at 4949 Broadway, Room F-249, Sacramento, California. The cost of these services shall be fully included in the cost of reagents noted in the first six line items of this Invitation for Bid.

Service shall be applicable for the equipment shown/provided by bidder on page 9 of the IFB.

STATE AGENCY CONTRACT LIAISON

The State's Department of Justice, Contract Liaison for this contract shall be Kenji Ota, Assistant Laboratory Director, (916) 227-3620. The Department of General Services, Procurement Division, and the Contract Liaison or Timothy A. Appel with the Department of Justice shall be solely responsible for determining acceptability of machine quality, operability, and satisfactory completion of any services provided by Contractor.

PREVENTATIVE MAINTENANCE

Contractor shall perform all maintenance services as specified herein and as necessary to maintain the optimum level of efficiency for each specified piece of equipment. Services shall include, as applicable, but not be limited to: cleaning, oiling, lubrication, adjustment, calibration, alignment, timing, replacement of any filters, and operational testing of each piece of equipment, furnishing all necessary lubricants, cleaning supplies, filters, and testing equipment, and providing any necessary repairs and parts replacement. Any parts requiring replacement will be replaced in accordance with the Parts Replacement section, Scope of Services.

Maintenance services shall be provided at no additional expense to the State for the full term of the contract by the contractor.

Any services performed by the Contractor are to be inspected by the State after completion. The State of California is solely responsible for determining acceptability of the work performed and the operability of the equipment.

All equipment requiring calibration shall be identified by placing inspection stickers on the equipment. The sticker shall show the date of calibration and/or date of service, and signature of service technician servicing the equipment. All instruments used to calibrate the equipment shall be certified and traceable to the National Institute of Standards Technology (NIST). Conductivity tests will be performed in accordance with applicable rules and regulations. Contractor shall maintain an instrument log book and provide a calibration certificate signifying that a continuing quality control program is in existence. The State reserves the right to review such log book.

PREVENTATIVE MAINTENANCE SCHEDULE

The contractor shall specify in writing the frequency and duration of schedule, which is mutually acceptable to the State and the contractor, which is consistent with the State's operating requirements and which is based upon the specific needs of the equipment.

Services shall be performed during normal business hours 8:00 a.m. – 4:00 p.m., Monday through Friday, State holidays and weekends excluded.

REMEDIAL MAINTENANCE

Remedial maintenance shall be commenced promptly after notification that equipment is inoperative. The contractor's maintenance personnel shall arrive at the State's installation site within 24 hours after notification by the State that remedial maintenance is required. If the repair cannot occur on the first working day of the state's call, the contractor shall advise the State of the reason for the delay and indicate when the repair will occur. Repair services will be performed during normal business hours 8:00 a.m. to 4:00 p.m., Monday through Friday, State holidays and weekends excluded. The State may, at its discretion, allow access to the equipment during nonbusiness hours when necessary subject to the State's security requirements.

Contractor shall make every attempt to complete repairs the same working day. Unless the repair requires part(s) that must be ordered, no repair may take longer than five (5) working days to complete. When a delay in repair will occur due to part(s) that must be ordered written notification must be sent via fax to Kenji Ota or Timothy A. Appel immediately with an estimated repair date and reason justifying delay.

Failure to respond to request for service as specified herein may be cause for liquidated damages to be assessed against the contractor (see Attachment C, Liquidated Damages.)

LOANED EQUIPMENT

For approved repair(s) lasting more than five working days, the State reserves the right to require the Contractor to provide loan equipment to the State at no additional cost. The equipment provided shall be the same or equivalent to the equipment being repaired. If loaned equipment is requested, Contractor shall provide the equipment to the State within 48 hours after notification in writing. Requests by the State for loaned equipment shall only be made for those pieces of equipment considered by the State to be vital to daily operations. Any loaned equipment provided by the Contractor to the State under this provision shall remain in the possession of the State until such repair has been completed and approved by Kenji Ota or Timothy A. Appel of Department of Justice. Kenji Ota or Timothy A. Appel are solely responsible for determining the length of time loaned equipment is to be provided to the State.

The State shall be relieved of all risks of loss or damage during the entire time the loan equipment is in the possession of the State, except when loss or damage is due to fault or neglect of the State. All loan equipment will be returned to the Contractors in good condition subject to reasonable wear and tear, except for any loss or damage arising from circumstances beyond the control of the State.

EOUIPMENT REMOVAL

Contractor shall endeavor to perform all services required under this agreement on State premises. In the event that equipment must be removed from State premises for repair, prior approval from Kenji Ota or Timothy A. Appel must be obtained. The Contractor shall be responsible for pickup and delivery from State premises. Upon completion of repair, the Contractor will notify the State to schedule a delivery date and time. Under no circumstances shall equipment removed from State premises be kept by the Contractor longer than five working days, unless prior written permission has been obtained from Kenji Ota or Timothy A. Appel

Before equipment may be removed from State premises, Timothy A. Appel shall record the serial number(s) of the equipment being removed and inspect the equipment. Upon return of the equipment by the Contractor, Kenji Ota or Timothy A. Appel shall check the serial number(s) against those previously recorded and inspect the equipment for acceptability.

PARTS REPLACEMENT

This agreement will include replacement of any part that becomes worn or inoperable, or that otherwise affects the equipment's operability in any way. The contractor will replace, without charge, nondisposable parts on all equipment supplied through the life of the contract.

Parts replaced including software updates by the Contractor under this agreement shall be new, factory manufactured, or of equivalent quality. Contractor agrees to maintain an adequate supply and/or be able to obtain within a reasonable amount of time any necessary replacement parts in order to perform repairs and maintenance in a timely manner. Consumables and other supply items are hereby excluded. (See page 9 of the first portion of the IFB, where consumable supplies are to be listed.) Any parts that have been replaced become the property of the Contractor.

Attachment B

WORKMANSHIP

All work provided by the Contractor shall conform to the latest requirements of Federal, State, City and County regulations. Contractor is responsible for compliance with all applicable laws, codes, rules and regulations in connection with work performed under agreement.

All services provided by the Contractor, including calibration, preventative maintenance, safety inspections, etc. must conform to all applicable City, County, State and Federal laws, ordinances, regulations, guidelines, pamphlets, circulation letters or any other applicable directive. This includes, but is not limited to Title 17 and Title 22, California Code of Regulations, California Rehabilitation Control Regulations, Subchapters 4 and 45, Chapter 5, Safety Orders of the State of California Division of Industrial Safety, Joint Commission of Accreditation of Hospitals Organization, American Hospital Association, College of American Pathologist, National Association of Fire Protection, California Occupational Health and Safety Administration, National Sanitation Foundation, and the State Fire Marshal's office.

The Contractor shall furnish the State with a "Certification of Compliance", signed by the service technician, acknowledging services were performed as indicated. If applicable, Contractor shall affix a certification seal to the equipment.

DOCUMENTATION REQUIREMENTS

After completion of service, the Contractor shall submit a complete report to the Kenji Ota or Timothy A. Appel of the service provided, including any necessary repairs. Report shall include: date of service, description of service provided, including replacement of any worn parts, name and signature of service technician, location of equipment, equipment make, model and serial number, description of any noted deficiencies and suggested corrective action, total labor hours expended, and signature of State employee certifying indicated services were performed.

REPLACEMENT OF REAGENTS

Reagents that are defective shall be replaced at no cost to the State.

EXCLUSIONS

Services provided under this agreement do not include maintenance of accessories, attachments, machines or other devices not specified herein. Also excluded are painting or refinishing of equipment, and the furnishing of supplies accessories, or devices of any nature, except such items or equipment as may be necessary for the maintenance and repair of the equipment.

This agreement does not include service, repair or replacement of parts required as a result of accident, neglect, abuse, misuse, alteration of equipment, or other improper operation, including but not limited to operation of equipment outside of its specified environmental conditions.

WORK AREA

Contractor will ensure that the work area is kept clean and free of debris, as necessary, to maintain a safe working environment for staff. While working on equipment, Contractor agrees to perform services with as little disruption to the State's operations as possible. All tools, equipment and other work materials belonging to the Contractor will be removed at the end of each working day. The State shall not be responsible for storage of any Contractor property.

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Attachment C

SPECIAL TERMS & CONDITIONS

SOLID-PHASE ENZYME IMMUNOASSAY SYSTEM FOR THE DETECTION OF DRUGS IN BIOLOGICAL FLUIDS

LIQUIDATED DAMAGES

The Contractor is obligated to complete services within the time frames specified herein. The time for completion of the work may be extended by mutual agreement for a reasonable period of time when there is a delay in the Contractor's performance of the work caused by unavoidable delay in receiving ordered parts, acts of God, fire, flood, epidemics, quarantine restrictions, strikes, freight embargoes, or unusual action of the elements, provided that the Contractor shall notify Kenji Ota in writing of the causes of delay within two days from the beginning of any delay. Liquidated damages shall not apply when the State has requested, and the Contractor has provided, loaned equipment within the time specified herein.

If the work is not completed within the time required, causing an unacceptable delay in the operability of the equipment, Contractor shall pay the State, as liquidated damages, the sum of money stipulated herein.

Liquidated damages are hereby set at the rate of \$100.00 per day for each 8 hour period day Contractor fails to respond to requests for service past the specified response time, or when Contractor fails to complete work past the specified service completion date.

If the Contractor fails to pay liquidated damages, the State may deduct the amount thereof from any money due or that may become due the Contractor under this agreement.

PRODUCTIVE USE REQUIREMENT

All products proposed as part of this automated system must have been installed and in productive use, in substantially the configuration proposed, for a paying customer external to the proposer's organization, for at least six (6) months prior to the required date of bid submission.

INVOICING

Invoices shall be sent to:

Department of Justice Toxicology Laboratory 4949 Broadway, Room F-249 Sacramento, California 95820-1528

ACCOUNTING PRINCIPLES

The Contractor will adhere to generally accepted accounting principles as outlined by the American institute of Certified Public Accountants. Dual compensation is not allowed. A Contractor cannot receive simultaneous compensation from two or more funding sources for the same services performed even though both funding sources could benefit.

MINIMUM WAGE

Contractor agrees to pay its employees wages not less than current minimum wage.

LICENSES AND PERMITS

The Contractor shall be an individual or firm licensed to do business in California and shall obtain at his/her expense all license(s) and permit(s) required by law for accomplishing any work required in connection with this contract.

In the event any license(s) and/or permit(s) expire at any time during the term of this contract, Contractor agrees to provide DOJ a copy of the renewed license(s) and/or permit(s) within thirty (30) days following the expiration date. In the event the Contractor fails to keep in effect at all times all required license(s) and permit(s), the State may, in addition to any other remedies it may have, terminate this contract upon occurrence of such event.

Contractor agrees that the State will have the right to review, obtain, and copy all records pertaining to performance of the contract. Contractor agrees to provide the State with any relevant information requested and shall permit the State access to is premises, upon reasonable notice, during normal business hours for the purpose of interviewing employees, inspecting, and copying such books, records, accounts, and other material that may be relevant to a matter under investigation for the purpose of determining compliance with Public Contract Code Section 10115 et seq. and Title 2, California Code of Regulations (CCR), Section 1896.60 et seq. Contractor further agrees to maintain such records for a period of three (3) years after final payment under the contract (Title 2, CCR Section 1896.75).

EMPLOYMENT OF EX-OFFENDERS

Contractor cannot be and will not either directly, or on a subcontract basis, employ in connection with this contract:

1. Ex-Offenders on active parole or probation;

- 2. Ex-Offenders at any time if they are required to register as a sex offender pursuant to Penal Code Section 290 or if such ex-offender has an offense history involving a "violent felony" as defined in subparagraph(c) of Penal Code Section 667.5; or
- 3. Any ex-felon in a position which provides direct supervision of parolees.

Ex-Offenders who can provide written evidence of having satisfactorily completed parole or probation may be considered for employment by the Contractor subject to the following limitations:

- 1. Contractor shall obtain the prior written approval to employ any such ex-offender from the Department of Justice, Authorized Administrator; and
- 2. Such ex-offender whose assigned duties are to involve administrative or policy decision-making, accounting, procurement, cashiering, auditing, or any other business-related administrative function shall be fully bonded to cover any potential loss to the State or Contractor.

INSURANCE REQUIREMENTS

Contractor shall furnish to the State a certificate of insurance after the award of the contract stating that there is commercial general and automobile liability insurance presently in effect for the contractor of not less than \$500,000 (additional amounts may be required) per occurrence for bodily injury and property damage liability combined.

The certificate of insurance must include the following provisions:

The insurer will not cancel the insured's coverage without 30 days prior written notice to the State; and

The State of California, its officers, agents, employees, and servants are included as additional insured, but only insofar as the operations under this contract are concerned.

Contractor agrees that the liability insurance herein provided for shall be in effect at all times during the term of this contract. In the event said insurance coverage expires at any time during the term of this contract, contractor agrees to provide at least 30 days prior to said expiration date, a new certificate of insurance evidencing insurance coverage as provided for herein for not less than the remainder of the term of contract, or for a period of not less than one year. New certificates of insurance are subject to the approval of the Department of General Services, and Contractor agrees that no work shall be performed prior to approval. In the event the Contractor fails to keep in effect at all times insurance coverage as herein provided, the State may, in addition to any other remedies, terminate this contract.

2 of 3

Attachment C

TUBERCULOSIS

Prior to performance of contracted duties, contractors and their employees who are assigned to work with inmates on a regular basis shall be required to be examined or tested or medically evaluated for tuberculosis in an infectious or contagious stage, and at least once a year thereafter or more often as directed by DOJ. Regular basis is defined as having contact with inmates in confined quarters more than once a week.

Contractor's and their employees shall be required to furnish to DOJ, at no cost to DOJ, a DOJ 7336 Employee Initial/Annual Tuberculosis (TB) Skin test and DOJ 7354 Infectious Free Staff Certification prior to assuming their contracted duties and annually thereafter, showing that the Contractor and their employees have been examined and found free of TB an infectious stage. The DOJ 7336 and the DOJ 7354 will be provided by DOJ upon Contractor's request.

BACKGROUND CHECKS

The State reserves the right to conduct a background check on the Contractor and/or the Contractor's personnel as the State deems necessary prior to award or during the term of the contract. The State further reserves the right to terminate the contract should a threat to security be determined.

NOTIFICATION OF PERSONNEL CHANGES

Contractor must provide to the State a list of names and phone numbers of their personnel at the beginning of the contract period. Contractor must notify the State of any changes of those personnel allowed access to State premises for the purpose of providing services outlined herein.

FINGERPRINTING

The Contractor and any employees of the Contractor may be subject to fingerprinting and clearance by the State through the Department of Justice, Bureau of Criminal Identification and Information.

INDEPENDENT CONTRACTOR

All services provided by the Contractor under this contract shall be performed as an independent contractor. The Contractor shall be responsible for withholding all applicable employee taxes.

CORPORATE STATUS VERIFICATION

Contractor, if a corporation, does certify under penalty of perjury that the corporation is currently in good standing with the Office of the Secretary of State and is qualified to do business in the State of California.

Attachment D

CALIFORNIA DEPT OF JUSTIC TOXICOLOGY LABORATORY

	Analyst: Chi	rol Nishimoto	<u>_</u> <u>_</u>	TOLK LIBIUA	te: 02/22/20	Benzodia	ch Number Cocaine	PCP	THC	
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